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By email to sherlock.scott@epa.gov

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Environmental Assistance Division
Office of Pollution Prevention and Toxics
Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460
United States of America

Re: FOIA Request No. EPA-HQ-2019-001853

Dear Mr. Sherlock:

This letter responds to your letter of December 20, 2018. In that letter, you requested BASF Colors & Effects Switzerland AG (BASF C&E) to indicate which portions of certain health and safety studies (the Studies) contain confidential business information (CBI) and to substantiate any CBI claims for the Studies. The Studies all relate to Pigment Violet 29, CAS No. 81-33-4. They are the subject of a request by Earthjustice and other NGOs under the Freedom of Information Act (FOIA).

Attachment 1 to this letter identifies the 8 Studies and the aspects of each of those studies for which BASF C&E and its European affiliates make confidentiality claims. They make no confidentiality claims for the other 16 of the 24 studies identified in the FOIA request. The rest of this letter provides relevant background information and substantiation for those claims and discusses other issues related to FOIA. Sanitized copies of the 8 studies for which confidentiality claims are made will be sent to you by email by our counsel.

SUMMARY

BASF C&E asserts confidentiality claims of two kinds: privacy claims under FOIA exemption 6, and CBI claims under FOIA exemption 4. Aside from the identification of individual laboratory personnel, BASF C&E and its European affiliates are asserting CBI claims

only for certain BASF-related information and some data included in or attached to the final study reports for the Studies.

Section 14(b)(2) of the Toxic Substances Control Act (TSCA) does not mandate disclosure of the Studies. The Studies are not subject to section 14(b)(2), because the Studies were not submitted under TSCA. Instead, they were submitted voluntarily to EPA by a Dutch company with the consent of the German owner of the Studies. Neither company is subject to TSCA or other U.S. laws. The predicate for the application of section 14(b)(2) is that a health and safety study was submitted “under this Act” (meaning TSCA). Because the Studies were submitted voluntarily, by persons not subject to TSCA, section 14(b)(2) does not apply to the Studies. Instead, EPA should proceed with a straightforward FOIA analysis.

EPA has a strong policy interest under TSCA in not disclosing the confidential aspects of the Studies. EPA risks losing future access to studies that it needs to implement section 6 if it makes the Studies publicly available.

In this case, EPA has received full copies of confidential studies cited in dossiers submitted by European companies under REACH. Under section 6 of TSCA, EPA is now and will in the future be evaluating the health and environmental effects of many chemical substances that are the subject of REACH dossiers. For those efforts, EPA believes it will need full copies of confidential studies on those substances cited in those dossiers. EPA generally cannot obtain those studies under its TSCA authorities, including section 8(d) and section 11(c), because the owners of those studies are European companies not subject to TSCA. Thus, in many cases, the only realistic hope that EPA has of obtaining full copies of those studies is through voluntary submissions. That is how EPA obtained the Studies in this case.

But European study owners would be very unlikely to make additional voluntary submissions of full copies of confidential studies in the future if in this case EPA were to disclose those full copies notwithstanding confidentiality claims by the owner of the Studies. Study owners invest heavily in studies, which have commercial value based in part on their remaining confidential. Public disclosure of confidential studies by EPA would destroy part of that commercial value. Thus, future voluntary disclosures to EPA of confidential studies without an assurance that the studies would remain confidential would mean that European study owners would have a substantial disincentive from submitting additional confidential studies to EPA.

BASF C&E and its European affiliates own confidential studies on chemical substances other than Pigment Violet 29, some of which are very likely to be of considerable interest to EPA under section 6. BASF C&E and its European affiliates will have little or no interest in providing full copies of those studies to EPA if EPA makes the confidential information in the Pigment Violet 29 studies publicly available.

Because section 14(b)(2) does not apply to the Studies, traditional FOIA law considerations apply here. They establish that the confidential information in the Studies is exempt from disclosure under FOIA. The data claimed as confidential qualifies as commercial or financial information obtained from a person and privileged or confidential. Accordingly, exemption 4 of FOIA applies, and the confidential information in the Studies is exempt from

disclosure. The *Critical Mass* criteria apply here since the Studies were submitted voluntarily. Nevertheless, the data claimed confidential also qualifies for exemption 4 under the *National Parks* criteria.

EPA's FOIA regulations, specifically 40 C.F.R. §§ 2.205(e) and 2.211(a), preclude EPA from exercising its discretion to disclose FOIA-exempt information, such as the confidential information in the Studies. Strong policy reasons support those regulations. Thus, EPA may not and should not disclose the full Studies.

FACTUAL BACKGROUND

BASF C&E or its European affiliates own the Studies. Robust summaries of the Studies are publicly available on the ECHA website. EPA included links to those robust summaries in its draft risk evaluation for Pigment Violet 29.¹ Those robust summaries do not include the data claimed as CBI.

On September 15, 2017, EPA's Maria Doa, Director, Chemical Control Division, Office of Pollution Prevention and Toxics (OPPT), sent a letter to Sun Chemical Group Coöperatief U.A. (Sun Chemical Group), located in the Netherlands. The letter stated that EPA was "requesting your cooperation to provide certain scientific studies" on Pigment Violet 29, and that "EPA is requesting that you provide this information voluntarily." Dr. Doa explained that EPA had directed this request to Sun Chemical Group because an affiliate of that company, Sun Chemical Corporation, manufactures Pigment Violet 29 in the United States. The letter cited no regulatory authority applicable to Sun Chemical Group. Instead, it reported that EPA needed the full study reports as part of its work under section 6 of TSCA with respect to Pigment Violet 29.

At that time, Sun Chemical Group did not have access to the Studies. Two of its European affiliates are registrants for Pigment Violet 29 under REACH, Regulation (EC) No 1907/2006. A BASF C&E affiliate based in Germany is the third registrant.² The three registrants are members of a Substance Information Exchange Forum (SIEF) for Pigment Violet 29. The SIEF agreement allows the other two Sun Chemical Group affiliates to cite the Studies in the dossier for Pigment Violet 29, but it does not provide rights of actual access to the Studies.

After receiving EPA's request, Sun Chemical Group approached BASF Colors & Effects GmbH with a request for access to the Studies for the sole purpose of providing them to EPA in response to EPA's request. The two companies entered into a Data Sharing Agreement for that purpose (Attachment 2). The Data Sharing Agreement provided that Sun Chemical Group was required to "make all reasonable efforts to ensure that disclosure of such Studies as required for the EPA's Purpose, shall only take place in a form (for example short summaries where possible) reflecting the minimum information required to be disclosed." As compensation for agreeing to enter into the Data Sharing Agreement, Sun Chemical Group agreed to pay BASF Colors & Effects GmbH 84,000 euros (equivalent to about \$95,600).

¹ Draft Risk Evaluation for Pigment Violet 29 (Nov. 2018), Appendices B-D, https://www.epa.gov/sites/production/files/2018-11/documents/draft_pv29_risk_evaluation_public.pdf.

² The three registrants are Sun Chemical A/S 7, Sun Chemical B.V., and BASF Colors & Effects GmbH.

Sun Chemical Group subsequently submitted complete copies of the Studies to EPA. In that submission, Sun Chemical Group claimed all of the information as CBI.

On December 4, 2018, Earthjustice submitted a FOIA request to EPA on behalf of several NGOs that requested complete (unsanitized) copies of the Studies, among other information.

On December 18, 2018, EPA's Mark Hartman, Acting Deputy Director for Management, OPPT, called the U.S. affiliate of BASF C&E (BASF Colors & Effects USA) to inform that company that EPA was preparing a letter to ask BASF C&E to substantiate CBI claims for the Studies. Mr. Hartman indicated that the substantiation would fall under the non-TSCA FOIA rules because the Studies were submitted voluntarily.

On December 20, 2018, EPA sent a letter to BASF C&E in Switzerland, asking it to substantiate the CBI claims that Sun Chemical Group had made. The letter indicated that a response must be sent by any of various means by the 15th working day after BASF C&E's receipt of the letter.

UPS delivered the letter to BASF C&E's postal office in Switzerland on December 24, 2018. BASF C&E had no working days for the rest of the year. The 15th working day after the December 24 receipt was January 22, 2019. On January 11, 2019, BASF C&E sent EPA a request for an additional 30 days in which to respond. EPA was initially unable to reply to this request due to the partial government shutdown that began on December 22, 2018. On February 1, 2019, Kevin Miller, Assistant General Counsel of EPA, informed BASF C&E by email that EPA granted the extension request.

DISCUSSION

1.0 TSCA Does Not Require Disclosure of the Data Claimed as Confidential, and EPA Should Not Disclose Them

Despite arguments that section 14(b)(2) of TSCA requires disclosure of health and safety studies submitted under TSCA, that provision does not apply here. The Studies were not submitted under TSCA. If EPA were nevertheless to disclose confidential information in the Studies on the basis of section 14(b)(2), it would be very unlikely in the future to receive access to other confidential studies cited in REACH dossiers on chemical substances that EPA is evaluating under TSCA section 6.

1.1 TSCA Section 14(b)(2) Does Not Require Disclosure of the Data Claimed as Confidential

EPA has included among the substantive criteria for use in making confidentiality determinations that "[n]o statute specifically requires disclosure of the information." 40 C.F.R. § 2.208(d). The NGOs that submitted the FOIA request have argued in comments on the draft risk evaluation for Pigment Violet 29 that TSCA section 14(b)(2) requires EPA to make the Studies

(and others) publicly available.³ In addition, a congressional letter to EPA asking for disclosure of the full Studies referred to section 14(b)(2) as the basis for the request.⁴ As explained below, however, section 14(b)(2) does not require disclosure of the data claimed as confidential, specifically or otherwise.

Section 14(a)(1) provides that that reverse-FOIA provision applies only to information “that is reported to, or otherwise obtained by, the Administrator under this Act.” Section 14(b)(2) modifies section 14(a)(1) with respect to “any health and safety study which is submitted under this Act.” The Studies were not submitted under TSCA, however. Thus, section 14(b)(2) does not apply to the Studies.

EPA’s FOIA regulations effectively define the term “submitted under this Act” in 40 C.F.R. § 2.306(b):

Information will be considered to have been provided under the Act if the information could have been obtained under authority of the Act, whether the Act was cited as authority or not, and whether the information was provided directly to EPA or through some third person.

EPA has no authority under TSCA over BASF C&E (a Swiss corporation) or BASF Colors & Effects GmbH (a German corporation). EPA also has no authority under TSCA over Sun Chemical Group (a Dutch corporation), for the same reason. Thus, EPA cannot conclude that the Studies were “reported to, or otherwise obtained by, the Administrator under this Act.”

The geographic scope of TSCA is limited to the United States.⁵ Unlike the Food and Drug Administration under some provisions of the Federal Food, Drug, and Cosmetic Act (FFDCA),⁶ EPA has no authority under TSCA over persons outside the United States. If it were to adopt a section 8(d) rule mandating submission of studies on a chemical substance, persons outside the U.S. would not be subject to the rule. If it were to issue a subpoena under section 11(c), persons outside the U.S. would not have to comply.

³ Letter of Dec. 6, 2018 to Dr. Nancy Beck from the Center for Environmental Health, Earthjustice, Environmental Defense Fund, Environmental Health Strategy Center, Natural Resources Defense Council, and Safer Chemicals Healthy Families (attached to comments of Environmental Protection Network (Jan. 14, 2019)); comments of Earthjustice and other NGOs (Jan. 14, 2019); comments of Environmental Defense Fund (Jan. 14, 2019). These comments are available in Docket No. EPA-HQ-OPPT-2018-0604.

⁴ Letter to Acting EPA Administrator Wheeler from Representatives Pallone and Tonko (Jan. 30, 2019), <https://energycommerce.house.gov/sites/democrats.energycommerce.house.gov/files/documents/EPA.2019.01.30.%20Letter%20Pigment%20Violet%2029.pdf>.

⁵ For example, section 8(b)(1) describes the TSCA Inventory as “a list of each chemical substance manufactured or processed in the United States.” EPA has always interpreted the scope of TSCA to be limited to chemicals in or entering the United States. See, e.g., 65 Fed. Reg. 16094, 16103 (Mar. 24, 2000) (“What is the Scope of TSCA Section 6 Authority? Section 6 of TSCA, 15 U.S.C. 2605, provides EPA with broad authority to issue rules to regulate the manufacture, processing, distribution in commerce, use, and/or disposal of chemical substances in the United States where such regulation is necessary to prevent unreasonable risks to health or the environment.”) (emphasis added).

⁶ See, e.g., FFDCA § 807, 21 U.S.C. § 384c, Inspection of Foreign Food Facilities, and FFDCA § 308, 21 U.S.C. § 2242, Foreign Offices of the Food and Drug Administration.

Neither Sun Chemical Group nor BASF C&E imports chemical substances into the United States. Neither one manufactures chemical substances in the United States, or processes chemical substances for distribution in U.S. commerce, or distributes them in U.S. commerce, or uses them in U.S. commerce, or disposes of them in U.S. commerce. Sun Chemical Group is located in the Netherlands. BASF C&E is located in Switzerland. Its affiliate BASF Colors & Effects GmbH is located in Germany. Thus, EPA has no statutory authority to require Sun Chemical Group or BASF C&E or its European affiliates to submit the Studies. Since the Studies were not submitted under TSCA, section 14(b)(2) does not require disclosure of confidential information in the Studies.

Notably, none of the NGO comments to the Pigment Violet 29 docket addressed or even acknowledged the question of whether section 14(b)(2) applies to the Studies. Similarly, the letter from Representatives Pallone and Tonko did not consider this issue. EPA must address this issue, however. When it does so, it will conclude that section 14(b)(2) is inapplicable here.

The TSCA provision of EPA's FOIA regulations asserts that "health and safety data are not eligible for confidential treatment." 40 C.F.R. § 2.306(g). However, that provision does not apply to the Studies. Another provision of that regulation states:

Applicability. This section applies to all information submitted to EPA for the purpose of satisfying some requirement or condition of the Act [TSCA] or of regulations which implement the Act, including information originally submitted for some other purpose and either relied upon to avoid some requirement or condition of the Act or incorporated into a submission in order to satisfy some requirement or condition of the Act or of regulations which implement the Act. Information will be considered to have been provided under the Act if the information could have been obtained under authority of the Act, whether the Act was cited as authority or not, and whether the information was provided directly to EPA or through some third person.

40 C.F.R. § 2.306(b). Since EPA could not have obtained the information under TSCA, the FOIA regulation does not apply to the Studies, including its statement that "health and safety data are not eligible for confidential treatment."

1.2 EPA Has a Strong Public Policy Interest Under TSCA in Protecting Voluntarily-Submitted Confidential Information From Disclosure

Here, EPA has successfully obtained access to complete copies of confidential studies cited in dossiers submitted under REACH. To the knowledge of BASF C&E, this is relatively unusual. Thus, how EPA handles this matter may set a precedent for future cases. Making the data claimed confidential public would almost certainly deter BASF C&E and its European affiliates as well as other companies outside the U.S. from allowing EPA to have access to non-public studies cited in dossiers submitted under REACH. This would substantially impair EPA's ability to obtain such studies for use in connection with TSCA section 6.

EPA needs voluntary submissions of studies, even if it must keep them confidential when they qualify for an exemption under FOIA. As it admitted many years ago:

... EPA needs access to business information in order to make informed decisions under the various laws that EPA is charged with implementing. Although some of these laws empower EPA to require submission of information, much time and effort would be required to actually compel production of information through court actions. Moreover, some extremely useful information is not subject to compulsory production, and may only be obtained voluntarily. EPA is therefore vitally interested in encouraging businesses to submit information on a voluntary basis. But businesses will cooperate in the submission of information only if they believe EPA will fairly evaluate confidentiality claims and withhold from public disclosure information which qualifies for confidential treatment.⁷

More particularly, EPA needs access to confidential studies cited in dossiers submitted under REACH for chemicals of interest under section 6. The Government Accountability Office has criticized EPA for not obtaining studies cited in REACH dossiers:

Without access to the data that companies have submitted to the European Chemicals Agency [under REACH] ..., regardless of the mechanism used, EPA is missing an opportunity to collect data that it has identified as an essential part of assessing chemical risk and future chemical regulation.⁸

REACH has required companies in the EU that manufacture or import chemicals to register those chemicals through submission of a dossier that summarizes required health and safety studies. The robust summaries of those studies are publicly available, but the studies themselves are not provided either to ECHA or the public. Overwhelmingly, those studies are confidential. Overwhelmingly, the study owners are European companies that are not subject to U.S. law. (Only importers into the EU and manufacturers in the EU are subject to REACH registration requirements.⁹) Thus, most studies cited for registration under REACH are under the control of persons who are not subject to TSCA, and EPA may not use its TSCA authorities to obtain those studies. As a result, EPA can only obtain access to those full studies (as opposed to the robust summaries) through voluntary submissions.

European data owners are very unlikely to provide EPA with confidential studies, however, if they know that EPA will make those studies publicly available. Data owners have invested large sums in paying for those studies to be conducted. The studies have commercial value that public release would destroy, at least in part. Accordingly, they would have a substantial disincentive to provide confidential studies to EPA if EPA will not keep them confidential. Certainly, BASF C&E and its European affiliates would be very unlikely to authorize additional submission of confidential studies to EPA if EPA makes full copies of the Studies public.

⁷ 40 Fed. Reg. 21987, 21989 (May 20, 1975) (notice of proposed rulemaking to adopt FOIA regulations).

⁸ GAO, Toxic Substances: EPA Has Increased Efforts to Assess and Control Chemicals but Could Strengthen Its Approach (Mar. 2013) at 17, <https://www.gao.gov/products/GAO-13-249>.

⁹ REACH Art. 6; see also Art. 8 (only representative of a non-Community manufacturer).

Even without access to full copies of studies cited in dossiers under REACH, EPA must still do its job under section 6. Section 21(k) directs EPA to take into consideration in activities under section 6 information that is “reasonably available to the Administrator.” Disclosure of confidential information in the Studies would likely mean that important information that would otherwise be “reasonably available” will not be available to EPA, however.

It is ironic that flawed arguments that TSCA requires disclosure of health and safety studies in this instance could result in EPA having less information available in which to make its prioritization decisions and to conduct its risk evaluations. That is the likely result if EPA were to make the confidential information in the Studies public.

2.0 Personal Information in the Studies Is Exempt From FOIA Exemptions 6 and 4

In general, the confidentiality claims identified in Attachment 1 relate to the following information for each study:

- Contact information for the study author(s) and the study sponsor.
- The names of individuals at the laboratory that conducted the study (but not their titles).
- Certain data or data tables and certain BASF-related information.

The first two items are claimed confidential for the protection of personal privacy. That information is exempt from disclosure under FOIA exemption 6, 5 U.S.C. § 552(b)(6), “personal and medical files and similar files the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.” Information identifying individuals at a laboratory is non-public information.

Some of the studies were conducted by laboratories affiliated with BASF C&E, and thus the laboratory personnel for those studies are employees of BASF C&E or its European affiliates. Other studies were conducted at a laboratory that is an entity of the Polish Government (Institute of Industrial Organic Chemistry, Ministry of Entrepreneurship and Technology, Poland).

The employees of these laboratories should not be subject to potential inquiries from the public due to the public release of the information claimed confidential.

In addition, the first two items are exempt from disclosure as CBI under FOIA exemption 4, 5 U.S.C. § 552(b)(4). Competitors of BASF C&E and its European affiliates could try to obtain technical or financial information from those individuals. Competitors could also try to recruit those individuals, resulting in the loss of valuable human assets. In addition, the substantiation presented below for the CBI claims for the data claimed confidential also applies to the personal information, since that information is critical for acceptance of the Studies as valid.

EPA accepted similar confidentiality claims for the names and contact information of technical contacts for Chemical Data Reporting rule reports. See the Final Confidentiality

Determination for FOIA Request No. EPA-HQ-2017-006623 (Appeal No. EPA-HQ-006425) (Jan. 11, 2018). It should do so here as well.

3.0 The Data Claimed Confidential Are CBI That Is Exempt From Disclosure Under FOIA Exemption 4

Exemption 4 exempts from FOIA requirements “trade secrets and commercial or financial information obtained from a person and privileged or confidential.” The bulk of the information claimed CBI in Attachment 1 relates to certain data or data tables. They qualify as commercial information obtained from a person that is confidential within the meaning of FOIA. Accordingly, EPA should not release the data claimed confidential due to exemption 4.

BASF C&E and its European affiliates have met all the requirements of EPA’s FOIA regulations. In particular, with reference to 40 C.F.R. § 2.208:

- (a) BASF C&E’s affiliate has asserted a business confidentiality claim to Sun Chemical Group and through Sun Chemical Group to EPA. Those claims have not expired or been waived or withdrawn. See the Factual Background discussion, above.
- (b) BASF C&E and its European affiliates have taken reasonable steps to protect the confidentiality of those aspects of the Studies claimed CBI. They intend to continue to take such measures. See section 3.3.
- (c) The information claimed CBI is not, and has not been, reasonably obtainable without the consent of BASF C&E or its European affiliates (other than governmental bodies) by use of legitimate means (other than discovery based on a showing of special need in a judicial or quasi-judicial proceeding). See sections 1.1, 3.4.4, and 3.5.2.
- (d) No statute, including TSCA, specifically requires disclosure of the information claimed CBI. See sections 1.1 and 3.4.4.
- (e)(1) Disclosure of the information is likely to cause substantial harm to the competitive position of BASF C&E and its European affiliates. See section 3.5.3.
- (e)(2) The information claimed CBI is voluntarily submitted information (see sections 1.1 and 3.4) and its disclosure would be likely to impair EPA’s ability to obtain necessary information in the future. See sections 1.2 and 4.2.

With reference to 40 C.F.R. § 2.204(e):

- (i) The information claimed confidential in the Studies is indicated by black blocks in the sanitized versions of the Studies. The sanitized information consists of personal information relating to laboratory personnel; certain BASF-related information; and certain data and data tables.
- (ii) BASF C&E requests EPA to refrain permanently from disclosing the information claimed confidential in the Studies. If EPA requires a specific number of years, BASF C&E requests that EPA keep that information confidential for a period of 10 years, subject to resubstantiation. The Studies reflect permanent aspects of Pigment Violet 29. So long as this chemical is subject to regulatory requirements but the Studies are not disclosed to the public, the Studies are likely to retain commercial value.

- (iii) The Studies were submitted by Sun Chemical Group to EPA in response to EPA's September 15, 2017 request. The submission occurred in early 2018, after Sun Chemical Group and BASF C&E's European affiliate entered into a Data Sharing Agreement dated February 28, 2018.
- (iv) At the request of BASF C&E and its European affiliates, Sun Chemical Group made a business confidentiality claim at the time it submitted the Studies to EPA. See the Factual Background statement, above. The December 20, 2018 EPA letter to BASF C&E notes that "Upon submission of this information to the Agency, you claimed all of this information as confidential business information ('CBI')."
- (v) BASF C&E and its European affiliates have taken several measures to guard against undesired disclosure to others of the information claimed confidential. See section 3.3.
- (vi) BASF C&E and its European affiliates have only disclosed full copies of the Studies to third persons under assurances of confidentiality, such as the Data Sharing Agreement.
- (vii) Neither EPA nor any other U.S. federal agency has previously made a confidentiality determination with respect to the information claimed confidential in the Studies. ECHA will, if provided copies of the Studies, accept them as confidential documents and handle them accordingly.
- (viii) Disclosure of the information claimed confidential would be likely to result in substantial harmful effects on the competitive position of BASF C&E and its European affiliates. See sections 3.1 and 3.5.3.
- (ix) The information claimed confidential was voluntarily submitted. See sections 1.1 and 3.4.4.

3.1 The Data Claimed Confidential Are Commercial Information

The terms "commercial or financial" are given their ordinary meanings. *Public Citizen Health Research Group v. FDA*, 704 F.2d 1280, 1290 (D.C.Cir.1983). Even with public disclosure of the robust summaries, the data claimed confidential remain valuable commercial information.

The commercial value of the Studies is amply demonstrated by the 84,000 euros that Sun Chemical Group paid BASF C&E for the right to send full copies of the Studies to EPA. The Data Sharing Agreement did not grant Sun Chemical Group the right to use the Studies for any other purpose. Sun Chemical Group or other companies may still approach BASF C&E or its European affiliates with a request to purchase other rights regarding the Studies. If EPA were to make the full Studies publicly available, however, those companies would have no incentive to purchase rights from BASF C&E or its European affiliates.

While Pigment Violet 29 is now registered under REACH, it is or will be subject to similar requirements in other jurisdictions (e.g., Korea, Turkey, Taiwan, and possibly China). The Studies will be critical for meeting those requirements. Public versions of the Studies without the data claimed confidential would be insufficient to meet those requirements. However, if the Studies were to be publicly available due to their public release by EPA, third parties could try to use those public versions of the Studies to meet those requirements.

Congress recognized in TSCA section 4 that health and safety studies can have commercial value to study submitters; thus, the data tables are “commercial information.” Section 4(c)(3)(A) provides that persons who submit health and safety studies required by EPA may be entitled to “fair and equitable reimbursement” from other companies benefiting by such submission. This provision, like the corresponding provisions in FIFRA, provides a mechanism by which the study owner is owed a measure of data compensation by others who benefit by submission of the study – typically, competitors – by avoiding the need to submit an equivalent study themselves.¹⁰

The courts have previously recognized similar studies as commercial information. See, e.g., *Public Citizen Health Research Group v. FDA*, 704 F.2d at 1290 (“Because documentation of the health and safety experience of their products will be instrumental in gaining marketing approval for their products, it seems clear that the manufacturers of IOLs have a commercial interest in the requested information.”); *Critical Mass Energy Project v. NRC*, 975 F.2d 871, 880 (D.C. Cir. 1992) (en banc), *cert. denied*, 507 U.S. 984 (1993) (safety reports).

Accordingly, the data claimed confidential for the Studies qualify as commercial information.

3.2 EPA Obtained the Data Tables From a Person

The EPA FOIA regulations define “person” to mean “an individual, partnership, corporation, association, or other public or private organization or legal entity, including Federal, State or local governmental bodies and agencies and their employees.” 40 C.F.R. § 2.201(a).

EPA obtained the data claimed confidential as part of the Studies submitted by Sun Chemical Group in response to its request of September 15, 2017. Sun Chemical Group qualifies as a “person.” Sun Chemical Group obtained the Studies from BASF C&E’s affiliate in order to be able to respond to EPA’s request. Thus, BASF C&E and its European affiliates are the real parties in interest here. BASF C&E and its European affiliates are also “persons.”

3.3 Reasonable Steps Have Been Taken to Protect the Confidentiality of the Data Claimed Confidential

BASF C&E and its European affiliates take reasonable steps to protect the confidentiality of the data claimed confidential. They have not published the Studies. They did not provide the Studies to the non-BASF registrants in the SIEF for Pigment Violet 29. The SIEF agreement provided the non-BASF registrants with only the right to cite the Studies in a dossier. The robust summaries on the ECHA website do not include the data tables. BASF C&E and its European affiliates have not made the Studies available to third parties or governmental entities without assurances of confidentiality. Access to the Studies within BASF C&E and its European affiliates is limited to individuals with a need to have access to them.

More generally, BASF C&E and its European affiliates take the following measures to maintain the confidentiality of information such as that claimed confidential in the Studies.

¹⁰ EPA has adopted rules implementing section 4(c)(3)(A) in 40 C.F.R. Part 791.

Those measures may be divided into four major areas: personnel access, site security, document security, and computer security.

- Personnel Access:

Access to confidential business information is restricted to individuals who specially require such information in order to adequately perform their job function and responsibilities. Persons other than BASF employees are not given access to electronic systems storing confidential business information. BASF employees who have access to confidential documents are trained on the importance of protecting sensitive information/ They are under obligation to ensure that confidential intellectual property is not made available to the competition/public. Confidential business information is not made available to the public nor to customers unless they have signed a non-disclosure agreement.

- Document Security:

All BASF confidential business information it is marked "CONFIDENTIAL." The information is kept in cabinets that are kept locked after office hours or whenever the responsible party is away from the area. Only the parties directly responsible for the confidential information are permitted to have keys. All confidential information is kept on site. Any confidential information which is to be discarded is first destroyed by on-site shredding or is discarded into a locked storage bin who contents is then shredded by a third part supplier.

BASF C&E and its European affiliates maintain information as confidential by employing such measures as (1) numbering and tracking all laboratory notebooks; (2) controlling information discussed with persons outside BASF C&E and its European affiliates by having a Supplier Contact Manager who controls and is present at all technical meeting with our suppliers; (3) controlling information discussed with persons outside BASF C&E or its European affiliates by management review of all information released to customer; (4) protecting information released in situations where there is technical collaboration between BASF C&E or its European affiliates and outside companies by means of secrecy agreements with long-term protection following termination of the relationship; and (5) informing employees of their obligation to hold such information a confidential if they should leave BASF C&E or its European affiliates.

- Computer Security:

Access to all computer information is protected by password security at the system, sub-system, and file levels, with different passwords for each. Passwords are assigned to individual on a limited need-to-know basis, are changed as required and are administered by the Manager, Information Technology as Security Administrator. Access to computer hardware is restricted by use of key lock and secret code systems. In addition to these measures, employees of BASF C&E and its European affiliates use a mandatory "smart card" to log in the individual computers. BASF C&E and its European affiliates use a robust firewall system to protect its network and information.

- Site Security:

When not occupied, the building is protected by an alarm system covering all entrances and spaces by the detection of sound. When the building is occupied, access at both front

and rear entrances is monitored by the security personnel. Both front and rear entrances are equipped with a key card system, which is electronically triggered to open only when proper identification is scanned. All visitors are requested to sign in. Visitors are accompanied by employees of BASF C&E or its European affiliates while on the premises.

These practices generally apply to all sites of BASF C&E and its European affiliates, and to the information in the Studies claimed confidential.

Further, the data claimed confidential are not readily discoverable through reverse engineering. The identity of the test chemical, Pigment Violet 29, is not confidential.

3.4 The Data Tables Are Confidential Under *Critical Mass*

3.4.1 The *Critical Mass* Criteria for Confidentiality

Under *Critical Mass Energy Project v. NRC*, 975 F.2d at 879, if commercial information is disclosed to the government voluntarily, it will be considered to be “confidential” for purposes of exemption 4 if it is the kind of information “that would customarily not be released to the public by the person to whom it was obtained.”¹¹ The data claimed confidential were submitted voluntarily, and they are the kind of information that BASF C&E and its European affiliates do not customarily release to the public.

BASF C&E has established above that the data claimed confidential are not the kind of information that it or its European affiliates would customarily release to the public. Instead, they take reasonable steps to ensure that these data and those in similar studies remain non-public. Thus, it only remains to show that the data claimed confidential were submitted voluntarily.

3.4.2 EPA Represented That Submission of the Studies Was Voluntary

EPA informed Sun Chemical Group that its submission of the Studies would be voluntary. The September 15, 2017 letter from Dr. Doa said, “EPA is requesting that you provide this information voluntarily.” In keeping with the voluntary nature of any submission, the letter also said, “I am requesting your cooperation” to provide the Studies; “EPA is requesting cooperation” to provide the Studies; and “EPA is requesting the full study reports.”

Similarly, when Mr. Hartman contacted the U.S. affiliate of BASF C&E by telephone on December 18, 2018, he indicated that the substantiation would fall under the non-TSCA FOIA rules because the Studies were submitted voluntarily.

The draft risk evaluation itself refers to the Studies as containing confidential information exempt from disclosure, presumably because the information was submitted voluntarily. It refers to “information protected as Confidential Business Information (CBI)” (page 5); “information

¹¹ See also, e.g., *Baker & Hostetler v. Dep’t of Commerce* 473 F.3d 312, 320 (D.C. Cir. 2006) (Kavanaugh, J.); *McDonnell Douglas Corp. v. NASA*, 180 F.3d 303, 304-05 (D.C. Cir. 1999); *Center for Public Integrity v. DOE*, 234 F. Supp. 3d 65, 74 (D.D.C. 2017).

protected under statute as Confidential Business Information (CBI) by the Toxic Substances Control Act (TSCA)” (page 6); and “information protected under statute as Confidential Business Information (CBI) by the Toxic Substances Control Act (TSCA) and therefore are not publicly available” (page 20).

These representations, both before and after submission of the Studies, reflected EPA’s acknowledgement that the Studies were submitted voluntarily.

3.4.3 A Submission Is Voluntary If EPA Could Not Require It

The courts have held that “if an agency has no authority to enforce an information request, submissions are not mandatory” (i.e., they are voluntary for purposes of *Critical Mass*). *Center for Auto Safety v. NHTSA*, 244 F.2d 144, 149 (D.C. Cir. 2001) (NHTSA had no authority to require respondents to provide certain information; held, submission was voluntary).¹² Where an agency could require a person to submit information that the agency has requested, the courts have held that the submission is mandatory (i.e., not voluntary).

EPA has incorporated in its FOIA regulations the concept of applicable statutory authority as affecting the voluntariness of submissions. There it defines “voluntarily submitted information” to mean:

business information in EPA’s possession –

- (1) The submission of which EPA has no statutory or contractual authority to require; and
- (2) The submission of which was not prescribed by statute or regulation as a condition of obtaining some benefit (or avoiding some disadvantage) under a regulatory program of general applicability, including such regulatory programs as permit, licensing, registration, or certification programs, but excluding programs concerned solely or primarily with the award or administration by EPA of contracts or grants.

40 C.F.R. § 2.201(i).

3.4.4 EPA Has No Statutory Authority to Require Submission of the Studies

It is clear that the Studies were submitted to EPA voluntarily, even under these interpretations of *Critical Mass*.

As an initial matter, Dr. Doa’s request for full copies of the Studies included no citation of authority applicable to Sun Chemical Group. The letter asked for the company’s “cooperation” and that the company “assist” EPA by providing the full study reports.

¹² See also, e.g., *Airline Pilots Ass’n, International v. USPS*, 2004 WL 5050900 (D.D.C. June 24, 2004) (USPS lacked authority to require Federal Express to submit redacted information; held, submission was voluntary); *Defenders of Wildlife v. Dep’t of Interior*, 314 F. Supp. 1, 16 (D.D.C. 2004) (“the ability to request information does not equate with the legal authority to compel the production of that information”; held, submission was voluntary); *Parker v. BLM*, 141 F. Supp. 71 (D.D.C. 2001) (BLM had no authority to require the information at issue; held, submission was voluntary)

As discussed in section 1.1, EPA does have authority to require persons subject to TSCA to submit studies in their possession, including under section 8(d) (relating to submission of health and safety studies). EPA also has subpoena authority under section 11(c). This authority does not apply to either Sun Chemical Group or BASF C&E or its European affiliates, however, since none of them is subject to TSCA.

The TSCA provision of EPA's FOIA regulations asserts that no health and safety studies may be considered to be voluntarily submitted, saying, "No information to which this section applies is voluntarily submitted information." 40 C.F.R. § 2.306(g). However, that provision does not apply to the Studies. Another provision of that regulation states:

Applicability. This section applies to all information submitted to EPA for the purpose of satisfying some requirement or condition of the Act [TSCA] or of regulations which implement the Act, including information originally submitted for some other purpose and either relied upon to avoid some requirement or condition of the Act or incorporated into a submission in order to satisfy some requirement or condition of the Act or of regulations which implement the Act. Information will be considered to have been provided under the Act if the information could have been obtained under authority of the Act, whether the Act was cited as authority or not, and whether the information was provided directly to EPA or through some third person.

40 C.F.R. § 2.306(b). As explained above, neither Sun Chemical Group nor BASF C&E nor its European affiliates submitted the Studies for the purpose of satisfying some requirement or condition of TSCA or its regulations, or for the purpose of avoiding some requirement or condition of TSCA or its regulations. EPA could not have obtained the Studies using its authority under TSCA, since neither person is subject to TSCA. Accordingly, § 2.306 as a whole does not apply to the Studies. This includes paragraph (g), with its statement that "[n]o information to which this section applies is voluntarily submitted information."

In summary, the data claimed confidential are confidential under all of the *Critical Mass* criteria.

3.5 The Data Claimed Confidential Are Confidential Under *National Parks*

3.5.1 The *National Parks* Criteria for Confidentiality

As shown above, the Studies were submitted voluntarily, and thus the *Critical Mass* criteria for confidentiality apply. In case EPA should disagree, however, it is also clear that the data claimed confidential meet the criteria for confidentiality of information that is not submitted voluntarily.

Those criteria were established in *National Parks and Conservation Ass'n v. Morton*, 498 F.2d 765 (D.C. Cir. 1974). *Critical Mass* limited these criteria to information that is not submitted voluntarily to an agency. The *National Parks* decision explained:

To summarize, commercial or financial matter is “confidential” for purposes of the exemption [FOIA exemption 4] if disclosure of the information is likely to have either of the following effects: (1) to impair the Government’s ability to obtain necessary information in the future; or (2) to cause substantial harm to the competitive position of the person from whom the information was obtained.

498 F.2d at 770 (footnote omitted). Public disclosure of the data claimed confidential would meet both the *National Parks* tests.

3.5.2 Impairment of the Government’s Ability to Obtain Other Studies

BASF C&E and its European affiliates own many toxicology studies, some of which may be of interest to EPA as it continues to implement section 6 of TSCA or for other reasons. Most of these studies remain unavailable to third parties except as BASF C&E or its European affiliates choose to provide access. When provided, access is generally premised on continued confidentiality, through either non-disclosure agreements or governmental commitments to maintain the studies as confidential. BASF C&E and its European affiliates would generally be unwilling to allow access without assurances of confidentiality. If EPA were to make the data claimed confidential for the Studies public in this case, it would consider that future direct or indirect disclosures to EPA would also likely result in loss of confidentiality. Accordingly, BASF C&E and its European affiliates would be much less likely to agree to make confidential studies available to EPA. This would make it much more difficult, or impossible, for EPA to obtain access to full copies of those studies.

3.5.3 Substantial Harm to the Competitive Position of BASF C&E and Its European affiliates

The courts have interpreted this prong of *National Parks* by concluding that parties opposing disclosure need not demonstrate actual competitive harm; instead, they need only show actual competition and a likelihood of substantial competitive injury in order to “bring commercial information within the realm of confidentiality.” *Public Citizen Health Research Group v. FDA*, 704 F.2d at 1291.¹³

As explained in section 3.1, the Studies are commercial information. That this commercial information has commercial value is evidenced by the 85,000 euros that BASF C&E AG received for the right to provide full copies of the Studies to EPA. If EPA were to make the data claimed confidential publicly available in full, BASF C&E and its European affiliates would be much less likely to receive additional payments for the Studies, since the Studies would be freely available on the EPA website.¹⁴

¹³ *Accord*, *New Hampshire Right to Life v. Dep’t of Health and Human Services*, 778 F.3d 43, 590 (1st Cir. 2015), *cert. denied*, 135 S. Ct 383 ((2015); *Watkins v. Bureau of Customs and Border Protection*, 643 F.3d 1189, 1194 (9th Cir. 2011); *Sharkey v. FDA*, 250 Fed. Appx. 284, 288 (11th Cir. 2007); *Lion Raisins Inc. v. Dep’t of Agriculture*, 354 F.3d 1072, 1079 (9th Cir.2004); *Utah v. Dep’t of Interior*, 256 F.3d 967, 970 (10th Cir. 2001).

¹⁴ EPA makes studies that it receives under TSCA publicly available at www.epa.gov/chemview.

While no other person is likely to pay for the right to provide these Studies to EPA, the Studies are very likely to be crucial for obtaining regulatory clearance to market Pigment Violet 29 in other jurisdictions. Often, it is the availability of underlying data, such as the data claimed confidential, that determines whether or not an unpublished study can be used by a competitor to support its notification or registration of a substance overseas without obtaining ownership or citation rights to use such data, depriving the data generator of the value of its investment in the underlying data. A study submitted voluntarily to EPA may also need to be submitted to a foreign regulatory agency. If EPA has made the underlying data from that study public, competitors would find it easier to use that study – without providing compensation to the original data owner to obtain data access or citation rights – to support their notification or registration of a substance under some foreign counterparts to TSCA.¹⁵

Accordingly, public disclosure of the data claimed confidential for the Studies by EPA would be likely to cause substantial harm to the competitive position of BASF C&E and its European affiliates.¹⁶

4.0 EPA May Not Disclose Information Exempt From Mandatory Disclosure Under FOIA

Under FOIA, EPA must disclose information that is the subject of a request unless subject to an exemption. If information is subject to an exemption, such as CBI exempt under exemption 4, however, FOIA does not require EPA to disclose it. On the other hand, FOIA does not prohibit EPA from disclosing information subject to an exemption either. See *Chrysler Corp. v Brown*, 441 U.S. 281 (1979). An agency generally has discretion to disclose exempt information. As discussed below, however, EPA has by rule greatly restricted its exercise of that discretion.

¹⁵ EPA under FIFRA requires persons citing a study owned by a third party to affirm that they have the study owner's permission to cite the study or have offered to pay data compensation to the study owner. 40 C.F.R. § 152.93(b). Similarly, REACH Article 30 requires SIEF members to pay compensation to other members who own studies needed for registration. Some other counterparts to TSCA do not have such a provision, however. For example, Japan, the Philippines, and Taiwan do not. For them, simply providing a copy of the study, however obtained, may be sufficient and there is no obligation to demonstrate affirmatively that the notifier or registrant has data access privileges. Competitors to the original data generator may be able to obtain full copies of a study from EPA because EPA disclosed it. Without underlying data, however, the study may not be deemed to meet the data requirement.

¹⁶ As EPA noted in adopting its FOIA regulations, “[t]he decision in *National Parks & Conservation Ass’n v. Morton*, 498 F.2d 765 (D.C. Cir. 1974), requires only a likelihood, not a substantial likelihood, that a business’s competitive position will be substantially harmed by Government disclosure of an item of information.” 41 Fed. Reg. 36902, 36921 (Sept. 1, 1976) (comment 39).

4.1 EPA FOIA Regulations Preclude EPA From Disclosing Information Exempt Under FOIA

This document has established that the information for which BASF C&E is making confidentiality claims is exempt from disclosure under FOIA. EPA may not disclose that information notwithstanding its discretion to do so. Its FOIA regulations state in 40 C.F.R. § 2.205(e):

If the EPA legal office determines that the information is entitled to confidential treatment for the full period requested by the business which made the claim, **EPA shall maintain the information in confidence** for such period, subject to paragraph (h) of this section, § 2.209, and the other provisions of this subpart which authorize disclosure in specified circumstances, and the office shall so inform the business.

(Emphasis added.) Thus, EPA has by rule precluded itself from exercising its discretion to disclose FOIA-exempt information except in narrow circumstances. Those special circumstances are described in 40 C.F.R. § 2.209 (e.g., disclosure to other federal agencies). None of those circumstances is applicable to this situation.

Further, 40 C.F.R. § 2.211(a) prohibits any EPA officer or employee from disclosing information “except as authorized by this subpart.” Other than in 40 C.F.R. § 2.209, Subpart B of Part 2 of 40 C.F.R. nowhere authorizes disclosure of FOIA-exempt information.

4.2 Strong Policy Reasons Support EPA’s Regulation Precluding Discretionary Disclosure of FOIA-Exempt Information

During the rulemaking in which it adopted its FOIA regulations, EPA confirmed that it would not exercise its discretion to disclose FOIA-exempt information except as provided in the regulations, even where persons argue that the public interest favors disclosure:

Comment – The proposed rule would preclude EPA from discretionary disclosures of information EPA has found to be entitled to confidential treatment. This is contrary to the public interest and will decrease EPA’s flexibility.

Response – The Administrator disagrees with this comment. A provision that EPA could disclose information by exercise of discretion, even if the information had been found to be entitled to confidential treatment, would conflict with the basic approach of the regulation, which is that businesses are entitled to know the extent of the protection EPA will afford the information submitted to them.¹⁷

Here, BASF C&E is entitled to know that EPA will protect from disclosure valuable commercial information in the form of confidential portions of the Studies that is exempt from disclosure under FOIA. EPA should not release that information notwithstanding the fact that it is FOIA-exempt.

¹⁷ 41 Fed. Reg. 36902, 36919 (Sept. 1, 1976) (response to comment 2).

As discussed in section 1.2, EPA has a strong public policy interest in access to studies cited in REACH dossiers concerning chemical substances for which EPA is conducting actions under TSCA section 6. Since only manufacturers and importers in the EU are subject to REACH registration requirements, it is highly likely that, as in this case, the studies cited in REACH dossiers are only in the possession of REACH registrants who are not subject to U.S. laws, including TSCA. The only way that EPA may obtain those studies is through voluntary submission. BASF C&E would not have authorized submission of the Studies to EPA in this case if it knew that EPA would make confidential information in the Studies public.

BASF C&E is not alone in this perspective. Studies required for REACH dossiers collectively cost billions of euros to conduct. They have substantial commercial value. As a result, their owners take extensive precautions to protect their investments in those studies, including disclosure to government agencies only with assurances that confidential information will not be disclosed to the public. EPA would face tremendous difficulty in obtaining any additional studies cited in REACH dossiers in the future if in this case it disclosed confidential information in the Studies.

In light of its own interests, as well as those of businesses that voluntarily submit information, EPA has described as one of the “basic principles” of its FOIA regulations that:

If the business does show that the information is entitled to confidential treatment, EPA should not release the information by exercising discretion it may possess to release it.¹⁸

EPA should follow that principle here.

CONCLUSION

TSCA does not apply to the Studies, so section 14(b)(2) also does not apply. TSCA does not require EPA to make confidential information in the Studies publicly available.

The personal information in the Studies is exempt under FOIA exemption 6 and exemption 4.

The data claimed confidential are exempt from disclosure under exemption 4, under both the *Critical Mass* criteria and the *National Parks* criteria.

EPA may not and should not exercise its discretion to disclose FOIA-exempt information in the Studies. Instead, it must and should keep that information confidential.

¹⁸ 40 Fed. Reg. 21987, 21988 (May 20, 1976).

For further communications regarding this substantiation or the FOIA request, please contact counsel for BASF Colors & Effects Switzerland AG, Mark Duvall at Beveridge & Diamond, P.C. in Washington, DC. He may be reached at (202) 789-6090 or at mduvall@bdlaw.com.

Sincerely,

A handwritten signature in blue ink, appearing to read "Ulrich Veith".

Dr. Ulrich Veith
Head of Product Stewardship and Masterdata
BASF Colors & Effects Switzerland AG

Attachments

cc: Erik Baptist
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ATTACHMENT A

List of Pigment Violet 29 Studies and Confidentiality Claims

The following is a list of the 8 Pigment Violet 29 studies for which BASF C&E is submitting sanitized copies for public disclosure. The following information has been deleted in some cases: personal information relating to laboratory personnel; certain BASF-related information; and data tables.

1. BASF 1999 study report. Local lymph node assay for Perylimid F. Report No. CTL/P/6194.
2. BASF 1999 study report. Determination of the biodegradability of Perylimid F in the manometric respirometry test according to GLP, EN 45001 and ISO 9002. Project No. 98/0291/26/1.
3. BASF 1999 study report. Determination of the Inhibition of Oxygen Consumption by Activated Sludge by Perylimid F in the Activated Sludge Respiration Inhibition Test according to GLP, EN 45001 and ISO 9002. BASF Project No. 98/0291/08/1.
4. Institute of Industrial Organic Chemistry, Branch Pszczyna, Poland 2012 study report. Paliogen Violet 5011, *Daphnia magna* acute immobilization test. BASF Project No. 50E00223/11X287.
5. Institute of Industrial Organic Chemistry, Branch Pszczyna, Poland 2012 study report. Paliogen Violet 5011, *Lemna gibba* L. CPCC 310 growth inhibition test. BASF Project No. 99E0223/11X541.
6. BASF 2012 study report. Gene mutation assay in Chinese hamster V79 cells *in vitro* (V79/HPRT) with Paliogen Violet 5011. Study No. 1443105. BASF Project No. 50M0223/11X116.
7. BASF 2013 study report. Physical-chemical properties of Paliogen Violet 5011. Study No. 11L00105.
8. BASF 2013 study report. Paliogen Violet 5011, Reproduction/Developmental Toxicity Screening Test in Wistar Rats Oral Administration (Gavage). Project No. 80R0223/11C162.

BASF C&E and its European affiliates do not claim the following 12 studies as confidential:

1. BASF. (1975a). Acute inhalation toxicity with rats. BASF report XXV/454. In Product Safety Basel. (XXV/454). Switzerland: BASF Schweiz AG.
2. BASF. (1975b). Acute oral toxicity with rats. BASF report XXV/454. (XXV/454). Switzerland: BASF Schweiz AG.
3. BASF. (1975c). Eye irritation / corrosion. [Note: This study is referenced in Appendix D of the draft risk evaluation, but the list of studies on pages 33-35 omits BASF 1975c; it goes from BASF 1975b to BASF 1975d.]
4. BASF. (1975d). Eye irritation study. BASF report XXV/454. In Product Safety Basel. (XXV/454). Switzerland: BASF Schweiz AG.
5. BASF. (1975e). Skin irritation study. BASF report XXV/454. In Product Safety Basel. (XXV/454). Switzerland: BASF Schweiz AG.
6. BASF. (1975f). Summary of toxicological investigations with CAS 81-33-4, Acute intraperitoneal toxicity with mice. BASF Report XXV/454. In Product Safety Basel. (XXV/454). Switzerland: BASF Schweiz AG.
7. BASF. (1978a). Study report for CAS 81-33-4, Acute inhalation toxicity with rats. BASF report 77/360. In Product Safety Basel. (77/360). Switzerland: BASF Schweiz AG.

8. BASF. (1978b). Study report for CAS 81-33-4, Acute intraperitoneal toxicity with mice. BASF report 77/360. In Product Safety Basel. Switzerland: BASF Schweiz AG.
9. BASF. (1978c). Study report for CAS 81-33-4, acute oral toxicity with rats. BASF report 77/360. In Product Safety Basel. (77/360). Switzerland: BASF Schweiz AG.
10. BASF. (1978d). Study report for CAS 81-33-4, skin irritation study. BASF report 77/360. In Product Safety Basel. (77/360). Switzerland: BASF Schweiz AG.
11. BASF (1978e). Eye irritation study. BASF report 77/360. In Product Safety Basel. (77/360). Switzerland: BASF Schweiz AG.
12. BASF. (1988). Testing the acute toxicity in the fish model Zebra danio (brachydanio rerio) over the course of 96 hours. Germany: Hoechst AG, Pharma Research Toxicology and Pathology.

BASF C&E and its European affiliates do not own the other 4 of the 24 studies that are the subject of the FOIA request. Accordingly, no confidentiality claims are made for those studies. They include the following:

1. Jung, R; Weigand, W. (1983). Perylimid study of the mutagenic potential in strains of salmonella typhimurium (Ames Test) and escherichia coli. (83.0695). Germany: Hoechst Aktiengesellschaft.
2. Rupprich, N; Weigand, W. (1984a). Perylimid testing the acute dermal irritant effects/caustic effects on the rabbit eye. (84.0228). Germany: Hoechst AG, Pharma Research Toxicology and Pathology.
3. Rupprich, N; Weigand, W. (1984b). Perylimid testing the acute irritant effects/caustic effects on the rabbit eye. (84.0229). Germany: Hoechst AG, Pharma Research Toxicology and Pathology.
4. Rupprich, N; Weigand, W. (1984c). Testing the acute oral toxicity in the male and female Wistar rat. (84.0225). Germany: Hoechst AG, Pharma Research Toxicology and Pathology.

Attachment 2

Data Sharing Agreement

Data sharing agreement

Between

BASF Colors & Effects GmbH, An der Rheinschanze 1, 67059 Ludwigshafen, Germany
(hereinafter referred to as "**Data Owner**")

and

Sun Chemical Group Coöperatief U.A.
Leeuwendeldseweg 3-T
1382 LV Weesp
The Netherlands
(hereinafter referred to as "**the Grantee**")

Hereinafter referred individually to as "**the Party**" or collectively to as "**the Parties**".

Preamble

Whereas the Data Owner holds rights on certain Studies relating to the Substance(s) and has the authority to grant rights to refer to, use and copy the Studies;

Whereas the Studies of the Data Owner may be of use for preparation of a risk assessment on the Substance by the US EPA pursuant to TSCA § 6(b)(4) (Title 15 USC § 2607(b)(4)), (collectively, "**EPA's Purpose**") and any risk management efforts following that risk assessment.;

Whereas the Grantee desires to use the Studies for submission to the US EPA for the EPA's Purpose;

Whereas the Data Owner is willing to provide such rights to the Studies for such purpose in accordance with the terms and conditions of this Agreement.

THE PARTIES HAVE AGREED UPON THE FOLLOWING:

Article I. Definitions

Terms written in initial capital letters are defined in the Preamble above, in this Article 1 or in other parts of this Agreement:

Affiliate: Any legal entity controlling, controlled by, or under common control with, either directly or indirectly, a Party. For these purposes, "control" shall refer to: (i) the possession, directly or indirectly, of the power to direct the management or policies of a person, whether through the ownership of voting rights, by contract or otherwise; or (ii) the ownership, directly or indirectly, of 50 % or more of the voting rights or other ownership interest of a person.



Full study report: a complete and comprehensive description of the activity performed to generate the information. This covers the complete scientific paper as published in the literature describing the study performed or the full report prepared by the test house describing the study performed

Robust study summary: a detailed summary of the objectives, methods, results and conclusions of a full study report providing sufficient information to make an independent assessment of the study minimising the need to consult the full study report;

Studies: the study/ies and information listed in Annex 1 in written or electronic form, and any copy/ies of the study summary/ies and/or robust study summary/ies and/or the full study reports which have been provided by the Data Owner.

Substance: Pigment Violet 29, otherwise identified as ((Anthra[2,1,9-def:6,5,10-d'e'f] diisoquinoline-1,3,8,10(2H,9H)-tetrone), or CAS Registry Number 81-33-4

Article II. License; confidentiality

1. The Data Owner provides the Grantee with copies of both the Robust study summaries as well as the Full study report(s) of the Studies.
2. Upon payment of the compensation set forth in Article III of this Agreement, the Data Owner grants to the Grantee for an indefinite period of time a non-exclusive and non-terminable right (license) to use the Robust study summaries and the permission to refer to the Full study reports.
3. The license is limited for the sole purpose of submission of the Studies to the US EPA for the EPA's Purpose.
4. The Grantee agrees:
 - (a) To treat all information contained in the Studies as confidential and to use the Studies only for the purpose specified in, and according to the terms of, this Agreement. Grantee undertakes to advise immediately Data Owner in writing of any disclosure or misuse by a third party of the Studies as well as of any request by competent authorities relating to the disclosure of that Information;
 - (b) To make all reasonable efforts to ensure that disclosure of such Studies as required for the EPA's Purpose, shall only take place in a form (for example short summaries where possible) reflecting the minimum information required to be disclosed;
 - (c) To make it available only to those employees, the Grantee's Affiliates (including their employees) or the Grantee's external consultants (including their employees) who need to have access to the Studies for the purpose specified in this Agreement and who are contractually or otherwise obligated to keep it confidential. The Grantee shall be responsible and accountable for the compliance of their Affiliates (including their employees) or external consultants (including their employees) with the obligations of this Article II.
5. Notwithstanding paragraph 4 above, in the event the Grantee or any of its Affiliates, as recipient of the Studies, makes a reasonable determination that it is required to disclose



- the Studies pursuant to a governmental and/or judicial obligation or order other than according to the EPA's Purpose, the Grantee will inform Data Owner in writing in due time of the disclosure and ask the recipient to maintain confidentiality.
6. The obligations specified in paragraphs 4 and 5 above shall not apply to Studies for which the Grantee can reasonably demonstrate that such Studies:
- (a) were known to the Grantee on a non-confidential basis prior to its disclosure pursuant to this Agreement;
 - (b) are publicly known at the time of disclosure or becomes publicly known thereafter without breach of the terms of this Agreement on the part of the Grantee;
 - (c) become known to the Grantee (without any restriction on disclosure) through disclosure by sources other than Data Owner, having a right to disclose such information; or
 - (d) were independently developed by the Grantee, any Affiliate and/or their employees, without access to Data Owner's Studies, as evidenced by documentary records.

Specific items of the Studies shall not fall within any exception merely because they are combined with more general information falling within any exception.

Article III. Compensation

1. In consideration for the licenses granted under Article II, the Grantee will compensate the Data Owner as set forth in Article III.2 with any taxes that may apply as set forth in Article III.3-4.
2. The compensation for these licenses will be effective by the payment to the Data Owner of the relevant lump-sum of 84000 EUR [eighty-four thousand EUR]. Payment is due within 30 [thirty] days after date of invoice.
3. All payments due hereunder shall be net payments, i.e. free of any bank or transfer charges or similar charges and without deduction of any taxes, levies or other dues payable. If payer is required to withhold any tax or to make any other deduction from any such payments, then the said payments shall be increased to the extent necessary to ensure that, after making of the required deduction or withholding, payee receives and retains (free from any liability in respect of any such deduction or withholding) a net sum equal to the sum which it would have received and so retained had no such deduction or withholding been made or required to be made (gross-up amount). If upon application of the beneficiary any withholding tax can be reduced, or refunded, or an exemption from withholding tax is granted, payer shall file on behalf of payee for such reduction, refund or exemption. Data Owner shall render any assistance to the Grantee to obtain such withholding tax reduction, refund or exemption. The Grantee shall be entitled to any refund of withholding taxes.
4. Indirect taxes, including but not limited to Value Added Tax (VAT), Goods and Service Tax (GST), service tax, business tax, as applicable pursuant to the relevant tax law, shall be borne by the Grantee. However, Grantee is entitled to withhold any payment of indirect



taxes unless payee has provided payer with a sufficient invoice for purposes of indirect taxation.

Article IV. Representations

The Data Owner represents that he is the owner of the Studies, and/or has authority to grant the rights granted or referred to under Article II.

Article V. Ownership of Information

1. This Agreement does not grant any ownership rights or change existing ownership rights to any of the Studies provided under this Agreement, in whatever form and whenever, by the Data Owner.
2. Neither this Agreement nor any disclosure of Studies shall vest any present or future rights in any patents, trade secrets or property rights and no license(s), except for those rights granted under Article II.

Article VI. Term & Termination

1. This Agreement and the license granted hereunder will have no expiration, except as provided under this Article VI.2-3.
2. This Agreement and the license provided hereunder shall expire once the Studies are no longer protected and may be used without restrictions under the applicable law.
3. Either Party may terminate this Agreement and the licenses granted under this Agreement, if the other Party is in material breach of any representation, warranty, covenant, or agreement contained in this Agreement, after providing written notice to the other Party of such intent and reason for termination. This termination will be effective sixty (60) calendar days after the date of sending the notice, unless before the end of that period the other Party cured the breach identified in the notice. If the breach is cured in the specified period and the breaching Party receives written acknowledgement from the non-breaching Party that the breach has been cured, then the notice of termination will be void and of no effect.
4. Upon the effective date of termination of this Agreement under Article VI.3 due to the Grantee's breach:
 - (a) All Studies, and the robust study summary prepared by Grantee, in whatever form will be promptly returned by the Grantee to the Data Owner;
 - (b) The Grantee will withdraw any Letter of Access for the Studies that was submitted to any regulatory agency;
 - (c) All rights granted to the Grantee will revert to the Data Owner upon the effective date of termination unless breach is cured under Article VI.3; and



- (d) The Grantee will have no claim against the Data Owner, for compensation of loss of business or goodwill for any other damages that may result from such termination of this Agreement.
- 5. Upon termination of this Agreement under Article VI.3 due to the Data Owner's breach, any compensation received by the Data Owner, under Article III will be returned to the Grantee within forty-five (45) calendar days of the effective date of such termination.

Article VII. Legal entity change

The consent of the other Party shall not be required in case a Party assigns, transfers or delegates its rights and obligations under this Agreement to any of its Affiliates or to a legal successor in ownership by sale, division, merger or consolidation of all or substantially the whole of the business relevant to the Substance referred to in this Agreement, subject to acceptance by the assignee of the terms of this Agreement, to be notified in writing to the other Party without undue delay.

Article VIII. Liabilities

- 1. It is the individual responsibility of the Grantee to critically assess the Studies that are made available. The Grantee assumes the full responsibility for its own use of the Studies so received. The Data Owner gives no warranty for acceptance by the US EPA of the Studies.
- 2. The Data Owner shall not be held liable for any direct, indirect or consequential loss or damage incurred by the Grantee in connection with the activities contemplated in this Agreement, unless caused by gross negligence or willful misconduct.
- 3. Nothing in this Agreement will be deemed to be a representation or warranty by the Data Owner of the accuracy, safety, or usefulness for any purpose of any technical information, techniques, or practices at any time made available by the Data Owner to the Grantee. The Data Owner will have no liability whatsoever should any part of the Studies be questioned in any manner or considered inaccurate, incomplete or insufficient for the purposes of inclusion in any regulatory registration/notification/application.

Article IX. Dispute resolution and applicable law

- 1. The Parties shall first attempt to settle amicably any dispute arising out of this Agreement. Any dispute shall be resolved by arbitration, ousting jurisdiction by ordinary courts, by a panel of three arbitrators. Each party to the dispute will nominate one arbitrator. These two arbitrators will then designate a third arbitrator who will also act as chairman. The arbitration decision shall be binding on the parties. The arbitration rules of the Deutsche Institution für Schiedsgerichtsbarkeit e.V. (German Institution on Arbitration) in Germany shall be applicable. The place of any hearing shall be in Frankfurt / Main, Germany and the language of the arbitration shall be English.

Each Party may at any time request from any competent judicial authority any interim or conservatory measure.



2. This Agreement shall be construed and be subject to the substantive laws of Germany.
3. If at any time any provision of this Agreement is or becomes invalid or illegal in any respect, this shall have no effect on the validity of the remaining contractual provisions. The invalid provisions are to be replaced, backdated to the time of their becoming ineffective, by provisions which come closest to achieving their objective.

The Parties by their duly authorized representatives, sign this Agreement in duplicate; with each Party receiving one of the signed originals hereof.

Wessp 14-12-2017
[Location], [Date]

Sun Chemical Group Coöperatief U.A.

[Signature]

F.M. Glaudemans,
man. Director

Ludwigshafen, 22.2.18 [Date]

BASF Colors & Effects GmbH

[Signature]

Jörg Leuninger
VP Global Portfolio & Innovation Mgmt